(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 September 2005 (01.09.2005)

PCT

(10) International Publication Number
WO 2005/079726 A1

(51) International Patent Classification[7]: A61H 31/00, A62B 7/00, 18/00, A61M 16/00

(21) International Application Number: PCT/NZ2005/000023

(22) International Filing Date: 18 February 2005 (18.02.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

531332	23 February 2004 (23.02.2004)	NZ
534606	6 August 2004 (06.08.2004)	NZ

(71) Applicants *(for all designated States except US)*: **FISHER & PAYKEL HEALTHCARE LIMITED** [NZ/NZ]; 15 Maurice Paykel, East Tamaki, Auckland, 1706 (NZ). **PRENTICE, Craig, Robert** [NZ/NZ]; 95 Kiwi Esplanade, Mangere Bridge, Auckland, 1701 (NZ).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MCAULEY, Alastair, Edwin** [NZ/NZ]; 58A Ngapuhi Road, Remuera, Auckland, 1005 (NZ). **GLEESON, Oliver** [NZ/NZ]; 19A Ropata Avenue Point England, 1006 Auckland (NZ).

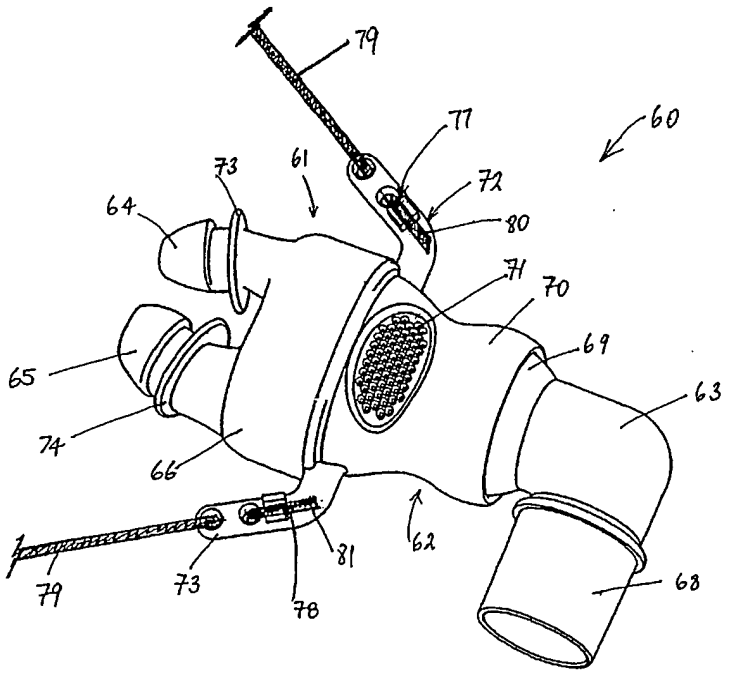
(74) Agents: **ADAMS, Matthew, D** et al.; A J Park, 6th Floor Huddart Parker Building, PO Box 949, Wellington, 6015 (NZ).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,

[Continued on next page]

(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: The present invention comprises a nasal cannula (2), shaped to fit within a user's nares, where the nasal cannula includes at least one prong (24, 25) allowing high flow delivery of humidified gases and creates positive airway pressure in the patient's airway. The prongs have angled ends (31, 32), such that in use, gases flowing through the prongs are directed to the user's nasal passages. The nasal cannula body is partially swivelling and preferably has a ball joint connector (37, 39). In another embodiment the nasal cannula may have at least one flared end prong (31, 32) that preferably seals within a patient's nare.

WO 2005/079726 A1

SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

"BREATHING ASSISTANCE APPARATUS"

FIELD OF INVENTION

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal positive airway pressure device.

SUMMARY OF THE PRIOR ART

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealingly engaged to a patient's face by means of a harness or other headgear. An exhaust port is provided in the delivery tube proximate to the mask. More sophisticated forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross-section outside the patient's nostril to a substantially oval cross-section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in

the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head; this headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks and the like are noisy (due to air leaks). These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a substantial number of such patients could benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

As oxygen is supplied as a dry gas it is well known in the art to either heat and/or humidify gases before delivering them for breathing by a patient. In particular when delivering oxygen, or oxygen or air mixture, it has proven beneficial to humidify the gases first. In WO01/41854 of Vapotherm, Inc. a system is disclosed that allows the delivery of humidified oxygen through a nasal cannula. This system uses a narrow bore conduit and nasal cannula with a high resistance to gas flows, thereby requiring the oxygen be of a high pressure. Air, as well as oxygen can also be passed down the conduit and nasal cannula and it too must be of a high pressure. This system allows the delivery of high flows of oxygen enriched air to the patient, but is limited in the flows achievable due to the narrow bore of the cannula resulting in high resistance gas flow and excessive velocity and noise upon exiting the cannula. Furthermore, the narrowness of the nasal cannula in this system allows easy expiration of gases between the prongs and nares and therefore does not create any positive airway pressure.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around itself and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a breathing assistance apparatus which goes someway to overcoming the above mentioned disadvantages or which will at least provide the public a useful choice.

Accordingly in a first aspect the present invention consists in a breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares, and adapted to deliver said humidified gases to said user,

a pressurised source of gases,

transportation means adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,

wherein said nasal cannula including at least one prong allowing high flow delivery of said humidified gases and creating a positive airway pressure in said patient's airway, said at least one prong having an angled end, such that in use, gases flowing through said prong are directed to said user's nasal passages.

In a second aspect the present invention consists in a breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares,

a pressurised source of gases,

transportation means adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,

wherein said nasal cannula are adapted to deliver said humidified gases to said user, said nasal cannula including at least one prong allowing high flow delivery of said humidified gases and creating positive airway pressure in said patient's airway, said at least one prong having an end that is flared outwardly.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a system providing humidified continuous positive airway pressure to a user as might be used in conjunction with a nasal cannula of the present invention.

Figure 2 is a perspective view of a first embodiment of the nasal cannula of the present invention.

Figure 3 is a side view of the nasal cannula of Figure 2.

Figure 4 is a plan view of the nasal cannula of Figure 2.

Figure 5 is a prong end view of the nasal cannula of Figure 2

Figure 6 is an exploded view of the nasal cannula of Figure 2.

Figure 7 is a side view of a second embodiment of a nasal cannula of the present invention.

Figure 8 is a side view of a third embodiment of a nasal cannula of the present invention.

Figure 9 is a perspective view of a fourth embodiment of a nasal cannula of the present invention.

Figure 10 is a side view of the nasal cannula of Figure 9.

Figure 11 is an exploded perspective view of the nasal cannula of Figure 9.

Figure 12 is a front view of the prongs of the nasal cannula of Figure 9.

Figure 13 is an exploded side view of the nasal cannula of Figure 9.

Figure 14 is a side cross-sectional view of a fifth embodiment of the nasal cannula of the present invention including a shield that protects an outlet vent from inlet gases.

Figure 15 is a cross-section through AA of the nasal cannula of Figure 14.

Figure 16 is a side cross-sectional view of a sixth embodiment of the nasal cannula of the present invention where the connection between a body part and connector of the cannula includes a plurality of channels.

Figure 17 is a cross-section through BB of the nasal cannula of Figure 16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Whether used in a hospital environment or in a home environment, the nasal cannula of the present invention will generally have associated three main pieces of apparatus. Firstly, an active humidifier, which that controls the temperature of a heater plate heating a body of water to achieve a desired temperature and humidity of the gases being humidified. Secondly, a transport conduit from the humidifier to the patient is also required, which is preferably heated to reduce condensation, or "rain out". Thirdly, a cannula designed to fit into the nasal cavity and deliver humidified, pressurized gases. In

particular, in one embodiment the nasal cannula of the present invention has two flared end prongs that seal within a patient's nares, although in some embodiments the cannula may have a single prong. The cannula prongs are shaped such that a step is created between them so that the prongs abut the user's nasal septum in use. Furthermore, the gripping action of the sides of the prongs to the user's septum in use prevents the prongs from dislodging from the user's nares. In another embodiment the prongs of the nasal cannula are angled toward one another as well as having an angled profile at the outlet of gases, such that gases flow from the prongs flows back into the nasal passage and is not forced up into the rest of the nasal cavity.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through the nasal cannula 2 of the present invention. The cannula 2 is connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 that contains a volume of water 6. The inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. The humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources; for example, temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. A flow of gases (for example air) is provided to the chamber through inlet 16 from a gases supply means or blower 15. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume

of the chamber above the water's surface and is passed out of the humidification chamber 5 through outlet 4. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

The blower 15 is provided with variable pressure regulating means or a variable speed fan 20 which draws air or other gases through the blower inlet 17. The speed of the variable speed fan 20 is controlled by the electronic controller 18 (or alternatively the function of the controller 18 could carried out by the controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via the dial 19.

Flared Prong Nasal Cannula

A first embodiment of a nasal cannula of the present invention is shown in detail in Figures 2 to 6. Referring to Figures 2 and 6, the nasal cannula 2 comprises three main components; the prong part 21, body part 22 and ball connector 23.

The prong part 21 has two nasal prongs 24, 25, each of which are substantially shaped to follow the contours of the human nares and in use are placed inside a user's nares. The prongs 24, 25 extend out from a hollow tubular body 26 that in use fits to the body part 22. Each of the prongs 24, 25 are integrally moulded with the tubular body 26 in a flexible plastics material or rubber, such as silicone, other thermoset elastomers or thermoplastic elastomers such as Kraton™. The prongs 24, 25 are substantially oval tubular members that allow for a passage of gases. In particular, as shown in Figure 5, the prongs are oval in shape and angled in the same manner as a human's nares. The prongs 24, 25 are angled toward one another (or toward the vertical axis Y) at the top 27, 28 of the prongs and away from one another at the bottom 29, 30 of the prongs. Furthermore, the ends 31, 32 of the prongs flare outwardly and preferably are formed such that the ends of the prongs are thinner in cross-section than the rest of the prongs. The flared thinner section ends 31, 32 of the prongs assist with the sealing of the prongs 24, 25 in use within the user's nares. When in use and with gases flowing through the prongs the force of the gas pressure will force the prong ends 31,32 to flare outwardly and seal against the inside of the user's nares.

The prongs 24, 25 each include a step 33, 34 formed along their lengths. Each of the steps 33, 34 are formed on the prongs 24, 25 in an opposing manner such that in use, when the prongs are within a user's nares the steps 33, 34 abut the user's nasal septum and form a ledge that prevents dislodgement of the prongs. The prongs 24, 25 also have protrusions 35, 36 formed on their outer edges that abut the sides of the user's nares

(opposite to the nasal septum). The protrusions 35, 36 assist in preventing the dislodgement of the prongs, especially if the user moves his or her head. The protrusions 35, 36 also maintain the prongs within the user's nares in a correct orientation such that in use gases flow through the prongs and directly up the user's nasal passages.

The body part 22 is a tubular passageway in which the prong part 21 is connected at one end and a ball joint 37 at the other end. The ball joint 37 extends from the connector 23 and slots into a complementary shaped (partial sphere) socket end 39. The body part 22 also has a number of apertures 38 formed in it, which act as a bias flow outlet vent. Therefore, any gases exhaled by the user through their nose will exit through the apertures 38.

The connector 23 is preferably connected to the inspiratory conduit 3 (see Figure 1) that supplies gases flow to the cannula 2. The inspiratory conduit 3 may be moulded directly to the connector 23 or other connection mechanisms may be used, such as a friction fit formed between the connector and conduit.

Although a ball and socket joint, as described above, between the body part 22 and connector 23 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the cannula body and connector must be able to be flexed or rotated to allow for the inspiratory conduit 3 to be moved without causing the dislodgement of the nasal cannula 2 from the user's nares.

In the preferred form of the nasal cannula 2 of the present invention the body part 22 and connector 23 are preferably made from a hard or rigid plastics material, such as polypropylene, polycarbonate or acetyl. In other forms the body part 22 and connector 23 may be of different plastics materials to allow for increased slidability between these parts.

The prong part 21 may be supplied in various different sizes such that different sized user's may remove an existing prong part and simply attach a different sized flexible plastics prong part over the body part 22.

To provide additional comfort for the user or ensure the nasal cannula of the present invention do not fall from a user's nares, the nasal cannula may be used in combination with a headgear strap. For example, Figure 1 shows a headgear strap 40 extending from the nasal cannula 2. The ends of the headgear strap that attach to the cannula may attach to extensions (or loops) 40, 41 on the body part 22 of the cannula shown in Figure 2, or may attach about other appropriate areas of the cannula, for example, about the connector 23.

The abovementioned embodiment of the nasal cannula 2 of the present invention is preferably a wide bore pronged cannula used for high flow conditions.

A second embodiment of the present invention is shown in Figure 7. In this embodiment of the nasal cannula 42 the prongs 43, 44 are preferably small bore prongs for use with lower flow conditions. The prongs 43, 44 are similarly shaped to the prongs 24, 25 detailed above, but may not seal in the same manner as the abovementioned prongs due to the smaller size of the prongs. In fact these prongs may not seal at all in use within the user's nares.

Furthermore, in this second embodiment the nasal cannula 42 is smaller and weighs less as it is only comprised of a prong body 45 and prongs 43, 44, where the body 45 is connected to a small tube that is formed with corrugations or bellows 48 that connect to an inspiratory tube or conduit 47 (similar to the inspiratory conduit 3 described above) that receives a supply of gases.

The corrugations of bellows 48 will bend or move when a weight or force is placed on the cannula, thereby preventing dislodgement of the cannula 42 from a user's face in use. In particular, the corrugations or bellows 48 prevent transferral of the torque onto the cannula 42 when a user moves his or her head.

The body 45 of the cannula 42 is provided with a number of apertures 48 that allows for gases exhaled by the users to be expelled into the ambient air.

The prong body and prongs of this embodiment of the cannula of the present invention are preferably formed a flexible plastics material or rubber, such as silicone, other thermoset elastomers or thermoplastic elastomers such as Kraton™.

A third embodiment of the nasal cannula of the present invention is shown in Figure 8 where the cannula may be provided with corrugated or baffled sections on the prongs. The nasal cannula 49 of this embodiment is similar to that of Figure 2 but the prongs 50, 51 have a series of corrugations 52, 53 formed in them. The corrugations 52, 53 allow for movement of each of the prongs 50, 51 for a better user fit, and allow for movement of the cannula 49 without causing dislodgement of the prongs from the user's nares.

Angled Prong Nasal Cannula

A fourth embodiment of the nasal cannula of the present invention is shown in Figures 9 to 13. The nasal cannula 60 has a similar construction to the nasal cannula of Figure 2 and comprises three main components; a prong part 61, body part 62 and ball jointed connector 63.

The prong part 61 preferably has two nasal prongs 64, 65, each of which are substantially shaped to follow the contours of the human nares and in use are placed inside a user's nares. In some forms a cannula with only one prong may be provided. The prongs 64, 65 extend out from a hollow tubular body 66 that in use fits to the body part 62, preferably about an extension 67 (as shown in the exploded view of the nasal cannula of Figure 11). Each of the prongs 64, 65 are integrally moulded with the tubular body 66 in a flexible plastics material or rubber, such as silicone, other thermoset elastomers or thermoplastic elastomers, such as Kraton™. The prongs 64, 65 are substantially oval tubular members that allow for a passage of gases.

In particular, as shown in Figure 12, the prongs are oval in shape (to reflect the shape of human nares) and angled in the same manner as a human's nares. The prongs 64, 65 are angled toward one another (or toward the horizontal axis X) such that angles α are formed between the midlines m, n through each respective prong 64, 65. The angled profile of the prongs 64, 65 means that they are more ergonomically correct with a human's nares and may assist in directing the gases flow from the prongs to the user's nasal cavities. The prongs 64, 65 are constructed such that their cross-sectional width narrows closer to the tip of each prong.

In the preferred form the prongs 64, 65 have an angled and profiled end 76 (see Figure 10). The angled ends 76 assist in directing gases flow to the user's nasal passages.

Each of the prongs 64, 65 has a flange 73, 74 disposed about its circumference. The flanges 73, 74 are at a position on the prongs 64, 65 such that the each of the flanges rests against the outside of each of the patient's nares. The flanges 73, 74 do not extend inside the nares, but rest at the entranceway of the user's nares, and preferably seal the nares. In some users the flanges 73, 74 may extend within the user's nares and provide sealing of the nares. The flanges 73, 74 are preferably thin flexible extensions that extend substantially completely around the circumference of the prongs 64, 65. The flanges 73, 74 are preferably substantially elliptical in shape with one side (for example, side 89, which in use will abut the nasal septum of a user) of the flange extending out from each prong further than the other side of each prong. There is a recessed area 88 on each of the prongs between the flange and the shaped ends of the prongs in which preferably in use the ends of a user's nares rest.

The body part 62 is a tubular passageway in which the prong part 61 is connected at one end and a ball joint 69 at the other end. The ball joint 69 extends from the connector 63 and slots into a complementary shaped (partial sphere) socket end 70 on the body part

62. The body part 62 may also have a plurality of apertures 71 formed in it, which acts as a bias flow outlet vent. Therefore, any gases exhaled by the user through their nose will exit through the apertures 71.

A shield 75 (illustrated by the dashed line in Figure 10) may extend over the bias vent 71 inside the body part 70 to prevent gases from the blower (gases supply 15) from interacting with the bias vent 71 and vent holes, causing noise in use.

In a sixth embodiment as shown in Figures 16 and 17 a nasal cannula without a prong part is shown, but that includes a shield similar to that described above. In this embodiment a body part 90 and a ball jointed connector 91 fit together as described above. The body part 90 includes an expiratory vent shield 92 that extends down from the top wall 94 of the body part 90 and shields the outlet vent 93.

Referring back to Figures 10 to 13, preferably the ball joint connector 63 is angled and extends into a swivelable connector 68. The swivel connector 68 is capable in use of being connected to the inspiratory conduit 3 (see Figure 1) that supplies gases flow to the cannula 60. The inspiratory conduit 3 may be moulded directly to the connector 68 or other connection mechanisms may be used, such as a friction fit formed between the connector 68 and the conduit 3.

In other forms of the present invention the ball joint connector 63 or the ball joint 69 may have formed in it a plurality of channels. One example of this is the embodiment of Figures 14 and 15. Such channels allow there to be a leak when gases flow through the connector to the cannula and prongs. The channels are therefore capable of acting as a bias flow and a separate bias flow out outlet (such as that outlet 71 described above) may not be required.

In Figures 14 and 15 only a body part 82 and ball jointed connector 83 are shown. The body part 82 and ball jointed connector 83 join in a manner as described above, where the substantially half sphere shaped end 84 of the body part 82 receives the substantially half sphere shaped end 85 of the connector 83. The ends 84, 85 enable a rotation between the body part 82 and connector 83. In this embodiment two channels 85, 87 are formed in the connector end 85. Two channels are shown in this embodiment but there may be only one or any number of channels. Similarly, channels may be formed in the body part end 84.

It is preferred that there is a ball and socket joint, as described above, between the body part 62 and connector 63, although other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the

cannula body and connector must be able to be flexed or rotated to allow for the inspiratory conduit 3 to be moved without causing the dislodgement of the nasal cannula 60 from the user's nares.

In the preferred form of the nasal cannula 60 of the present invention the body part 62, connector 63, ball joint 69 and swivel connector 68 are preferably made from a hard or rigid plastics material, such as polypropylene, polycarbonate or acetyl. In other forms these may be of different plastics materials to allow for increased slidability between these parts.

The prong part 61 may be supplied in various different sizes such that different sized user's may remove an existing prong part and simply attach a different sized flexible plastics prong part over the body part 62.

To provide additional comfort for the user or ensure the nasal cannula of the present invention does not fall from a user's nares, the nasal cannula 60 is preferably used in combination with a headgear strap. The strap may be similar to that shown in Figure 1 with relation to the first form of the nasal cannula 2. In this fourth form of the nasal cannula 60 the body part 62 has headgear extensions 72, 73 that extend out from the body part 70. The extensions 72, 73 each have a channel 77, 78 formed in them that is capable of receiving an end 80, 81 of the headgear strap 79. The strap ends 80, 81 in use are threaded through apertures (preferably two) and extend into and are held in the channels 77, 78. In this form the headgear strap 79 is made from a small diameter silicon, rubber or similar type material. Therefore, when the strap ends 80, 81 are threaded through the apertures friction is created that maintains the straps within the apertures and prevents the straps from slipping from the cannula.

In other forms the ends of the headgear strap that attach to the cannula may attach to extensions (or loops) 40, 41 on the body part 22 of the cannula shown in Figure 6, or may attach about other appropriate areas of the cannula, for example, about the connector 23.

WE CLAIM:

1. A breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares, and adapted to deliver said humidified gases to said user,

a pressurised source of gases,

transportation means adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,

wherein said nasal cannula includes at least one prong that is capable of high flow delivery of said humidified gases and creates a positive airway pressure in said patient's airway, said at least one prong having an angled end, such that in use, gases flowing through said prong are directed to said user's nasal passages.

2. A breathing assistance apparatus according to claim 1 wherein said nasal cannula includes arms or loop to attach a head strap to said cannula.

3. A breathing assistance apparatus according to claim 2 wherein said head strap is a small flexible tube.

4. A breathing assistance apparatus according to any one of claims 1 to 3 wherein said at least one prong includes a flange near or about its end.

5. A breathing assistance apparatus according to any one of claims 1 to 4 wherein said at least one prong is two prongs that are angled toward one another and are oval in shape such that they substantially follow the shape and contour of human nares.

6. A breathing assistance apparatus according to claim 4 wherein said flange causes the sealing of said at least one prong in at least one nare of said user in use.

7. A breathing assistance apparatus according to claim 4 or 6 wherein said flange is a thin flexible extension that extends substantially completely around the circumference of said at least one prong.

8. A breathing assistance apparatus according to any one of claims 4, 6 or 7 wherein said flange is elliptical in shape with one side of said flange extending out from said at least one prong further than the other side.

9. A breathing assistance apparatus according to any one of claims 1 to 8 wherein said at least one prong includes a flange, recessed area and shaped end where the recessed area is disposed between said flange and said shaped end and in use said flange extends into and seals within a user's nares.

10. A breathing assistance apparatus according to claim 9 wherein said shaped end becomes progressively thinner in cross-section towards its tip.

11. A breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares,

a pressurised source of gases,

transportation means adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,

wherein said nasal cannula are adapted to deliver said humidified gases to said user, said nasal cannula including at least one prong allowing high flow delivery of said humidified gases and creating positive airway pressure in said patient's airway, said at least one prong having an end that is flared outwardly.

12. A breathing assistance apparatus according to claim 11 wherein said flared end of said at least one prong at least partially seals within said user's nares in use.

13. A breathing assistance apparatus according to claim 10 or 11 wherein said nasal cannula has two nasal prongs.

14. A breathing assistance apparatus according to claim 13 wherein said prongs are oval and shaped to follow the contours of human nares.

15. A breathing assistance apparatus according to claims 13 or 14 wherein said prongs are angled toward one another to prevent dislodgement from said user's nares and assist in flow of gases into the user's nasal passages.

16. A breathing assistance apparatus according to any one of claims 13 to 15 wherein said prongs each have a step formed in them such that in use the sides of said prongs abut the user's nasal septum so as to prevent said prongs from dislodging from said user's nares.

17. A breathing assistance apparatus according to claim 16 wherein each of said prongs include a protrusion formed opposite said step that assists in correct orientation of said prongs within said user's nares.

18. A breathing assistance apparatus according to any one of claims 10 to 17 wherein said nasal cannula includes a body that has a plurality of apertures that act as a bias flow outlet vent for gases exhaled by said user.

19. A breathing assistance apparatus according to any one of claims 10 to 18 wherein said nasal cannula is connected to said transportation means by way of a ball and socket joint.

20. A breathing assistance apparatus according to any one of claims 10 to 8 that further 19 includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases,

21. A breathing assistance apparatus as herein described with reference to the accompanying figures.

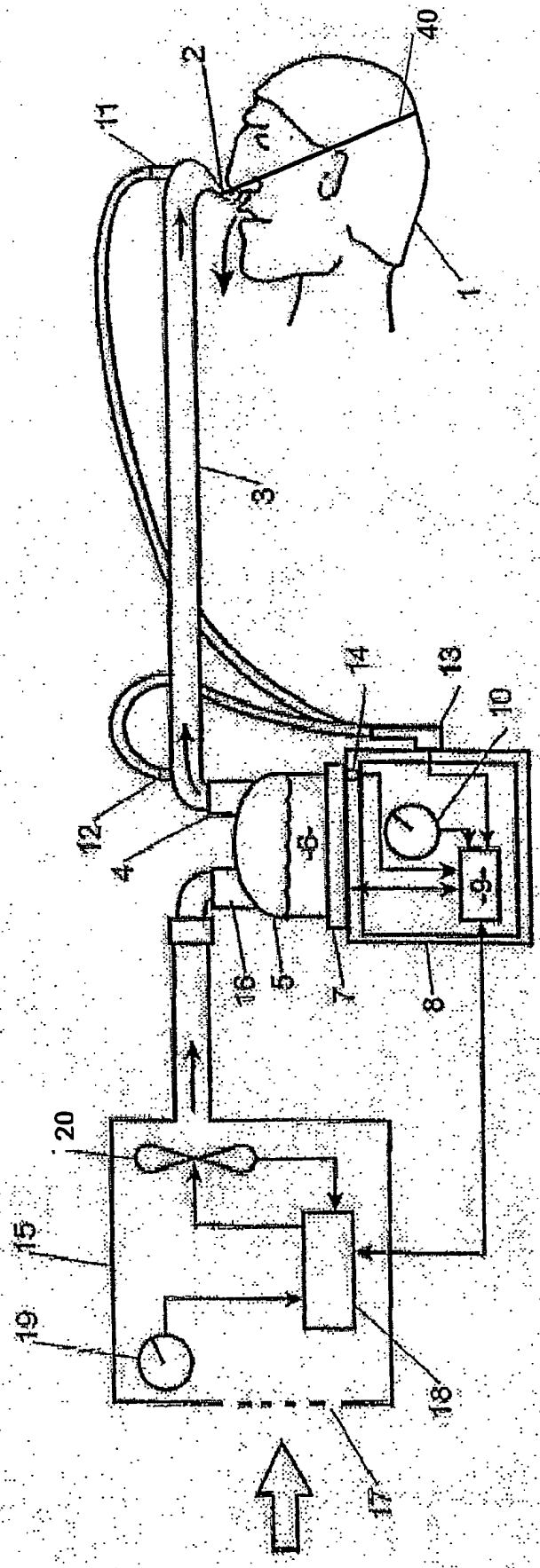


Figure 1

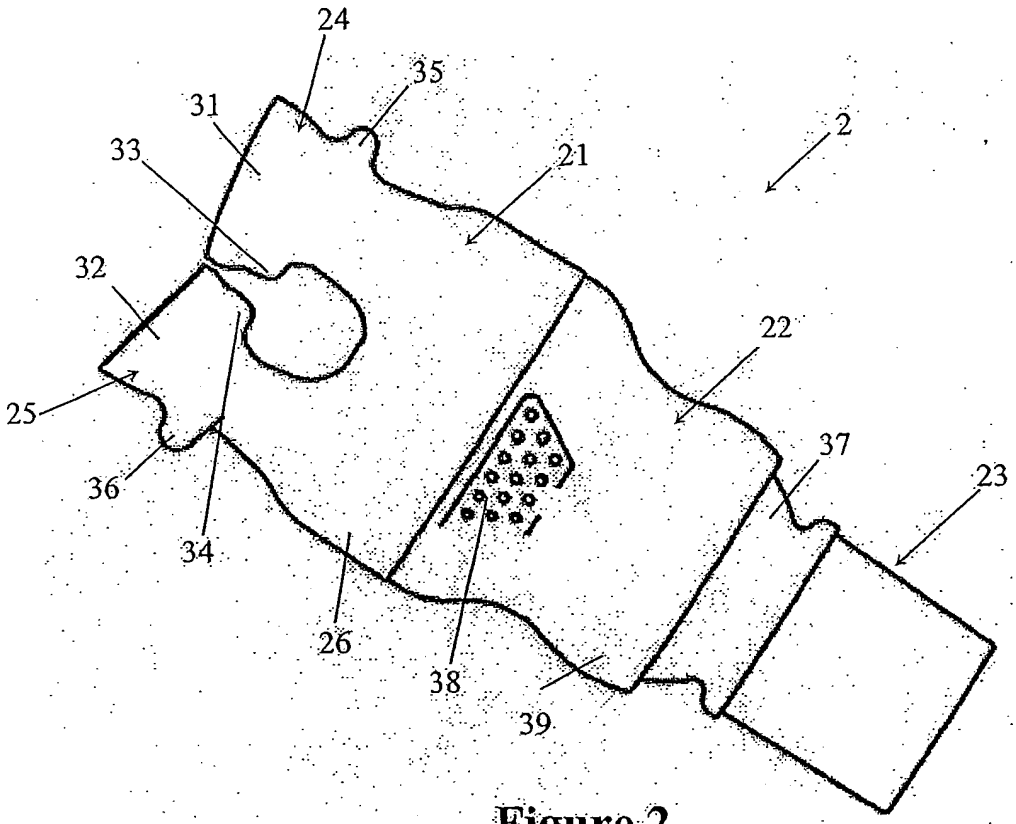


Figure 2

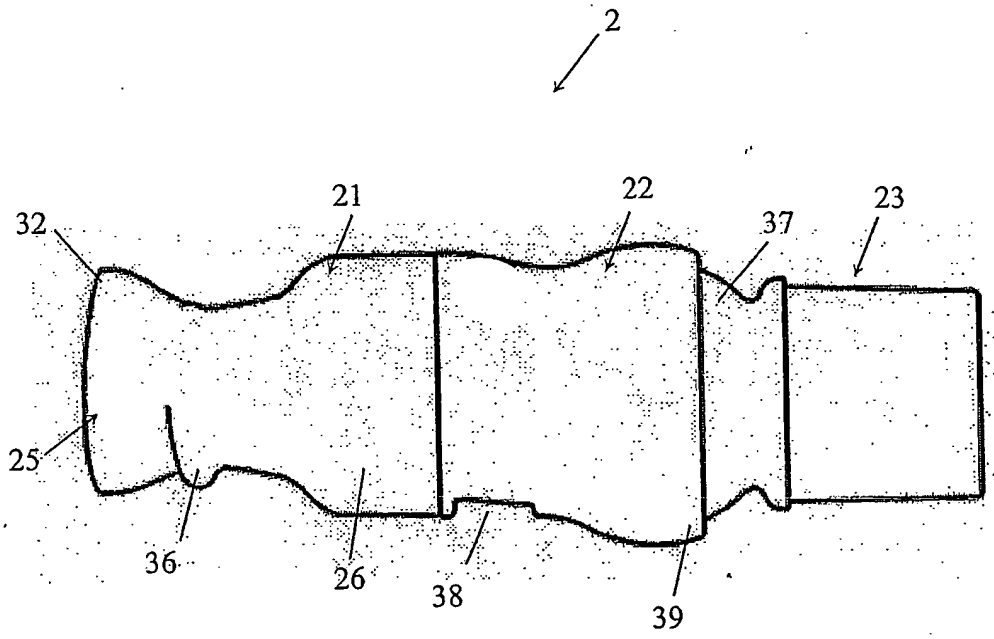


Figure 3

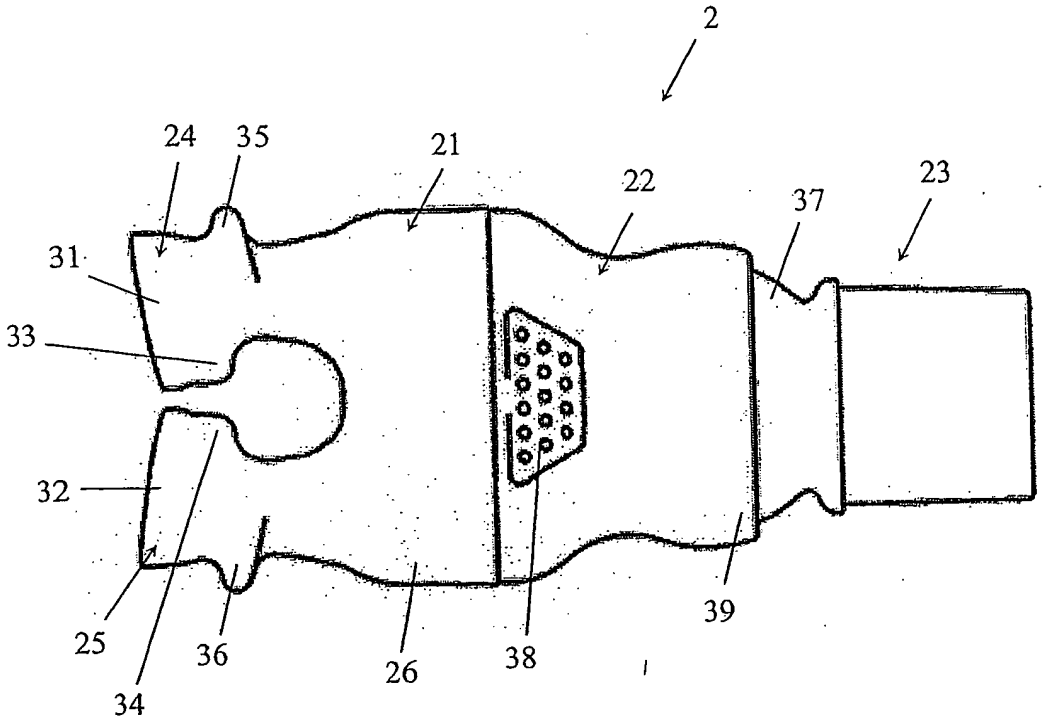


Figure 4

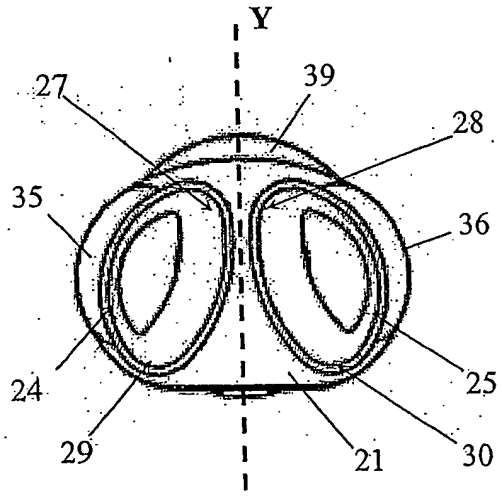


Figure 5

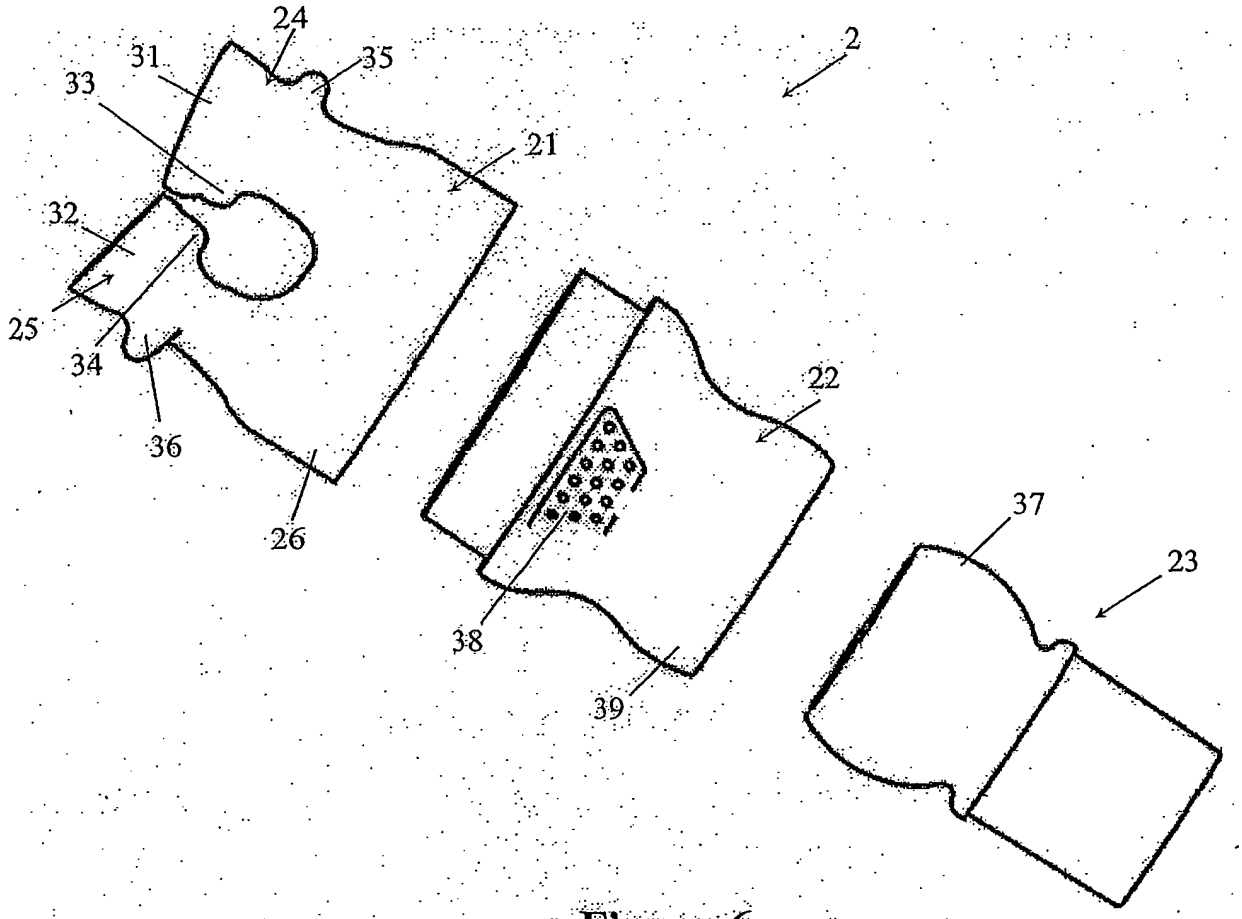


Figure 6

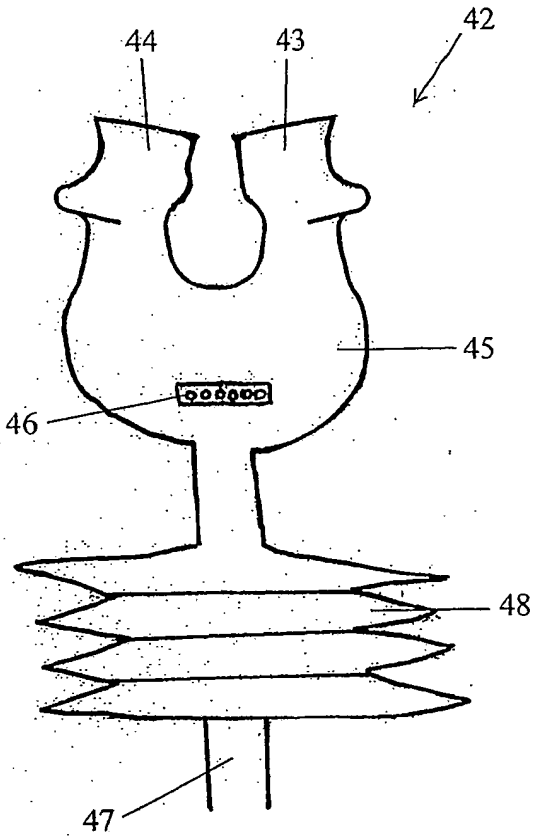


Figure 7

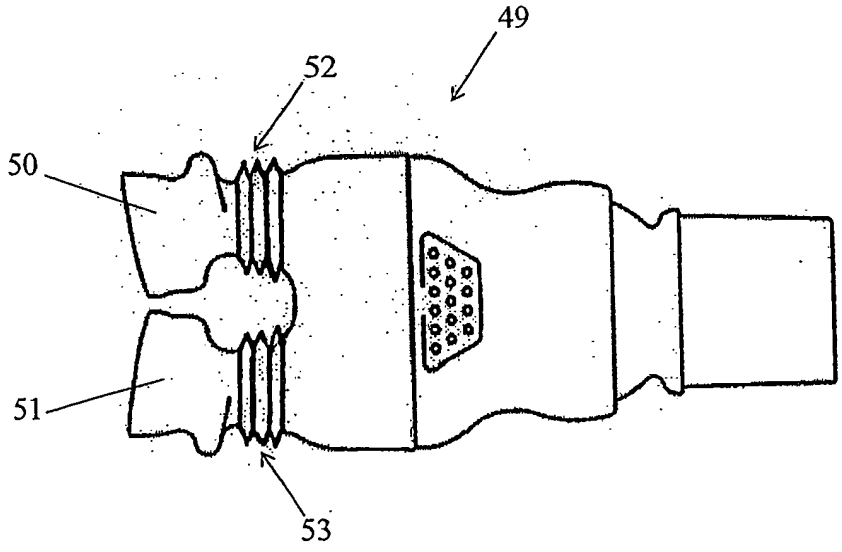


Figure 8

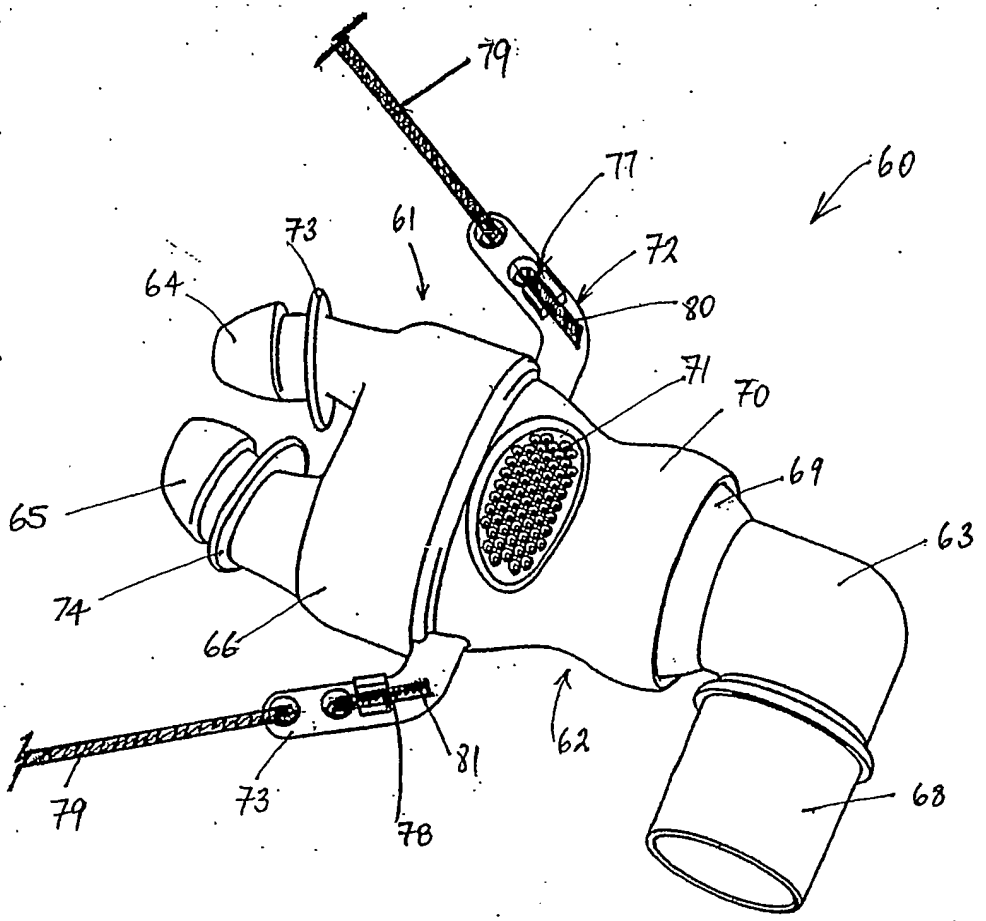


Figure 9

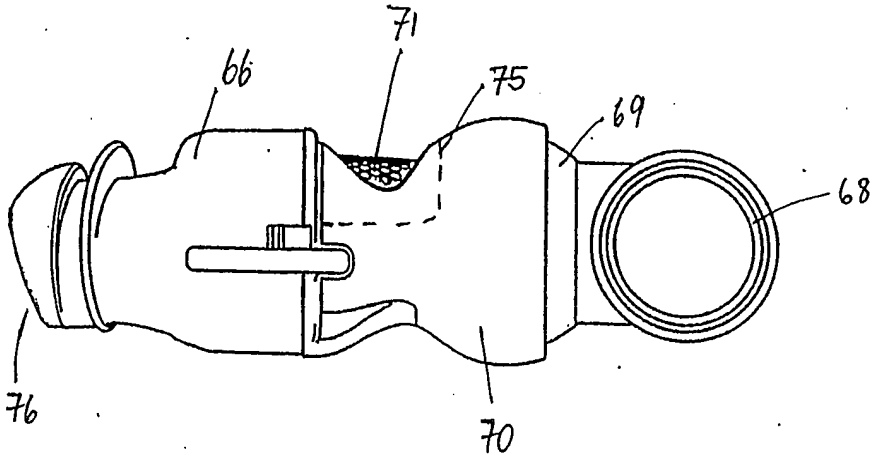


Figure 10

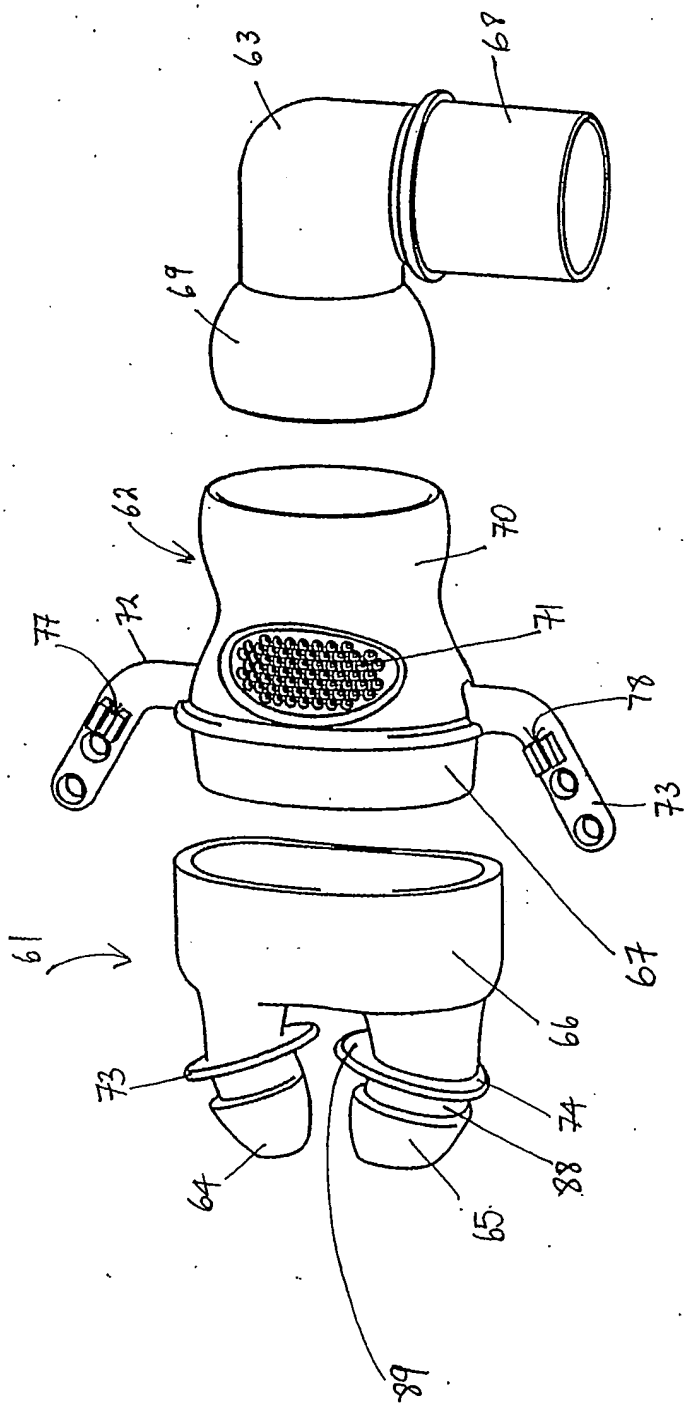


Figure 11

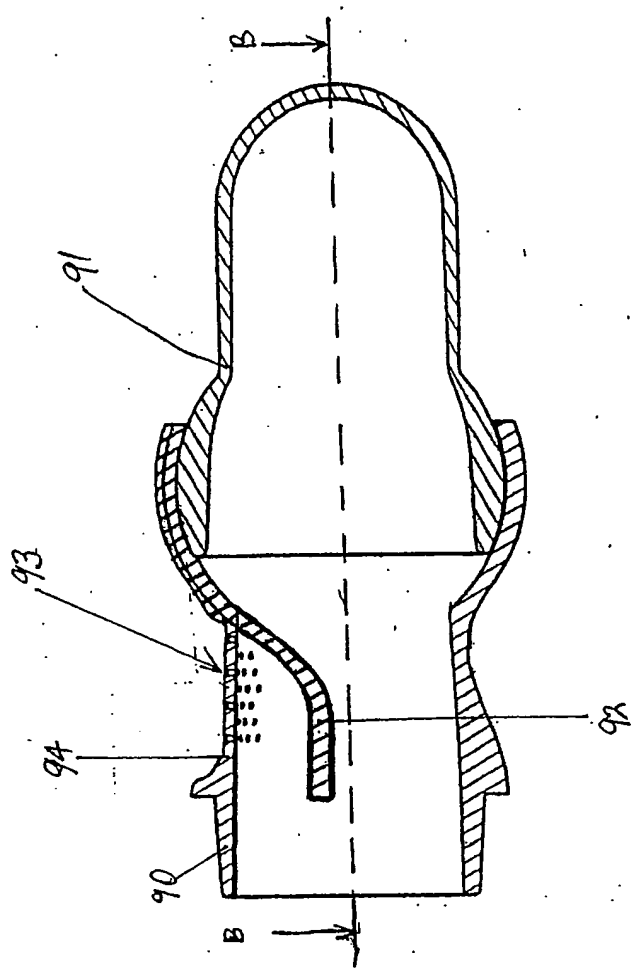


Figure 16

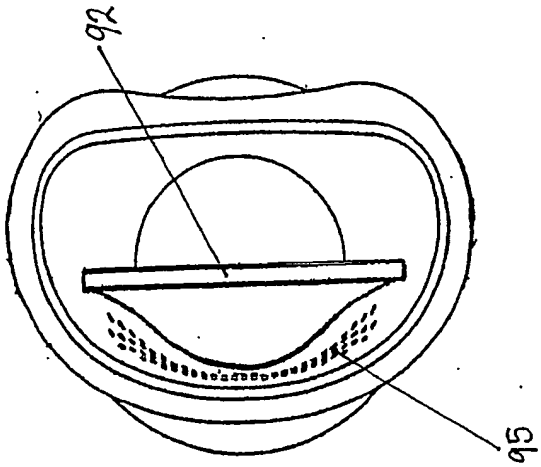


Figure 17

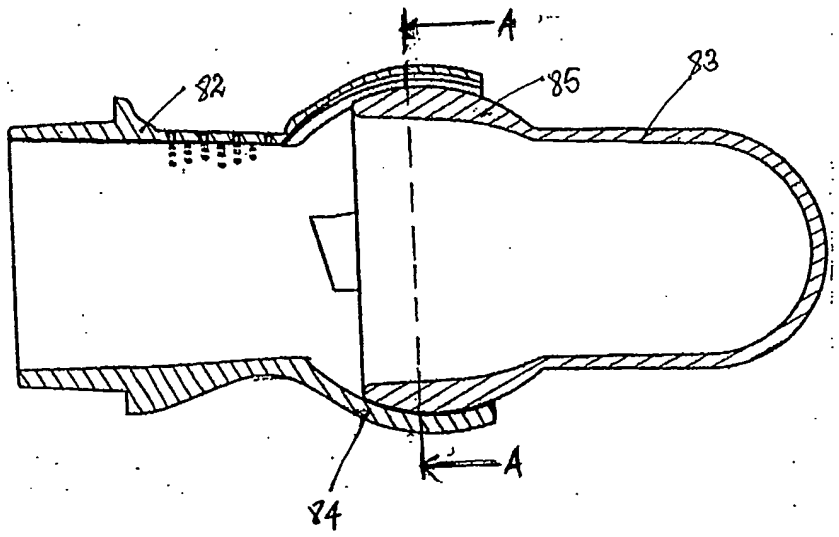


Figure 14

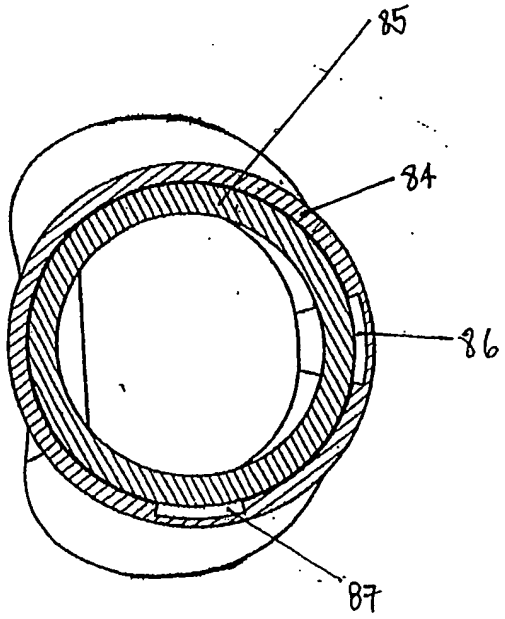


Figure 15

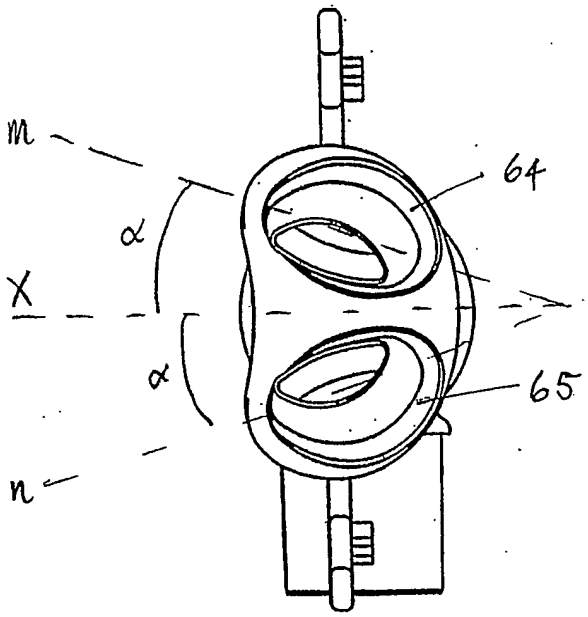


Figure 12

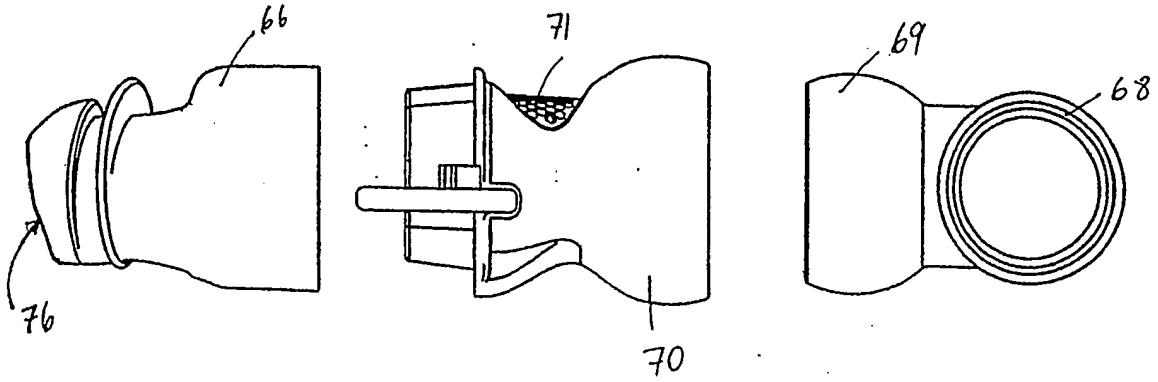


Figure 13

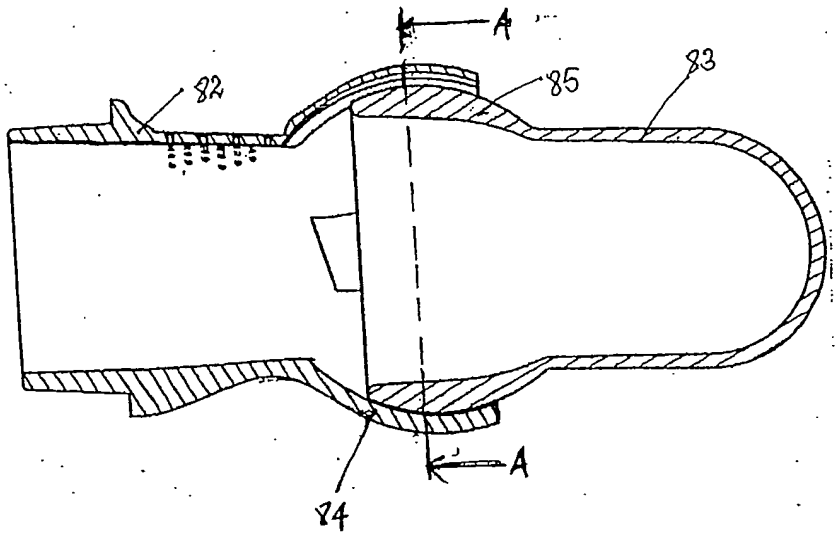


Figure 14

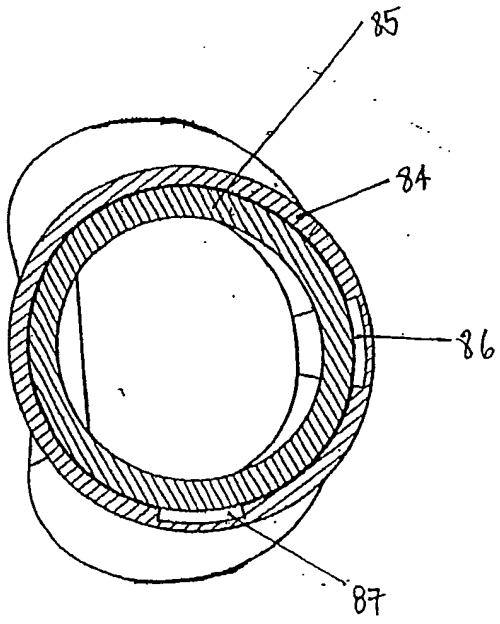


Figure 15

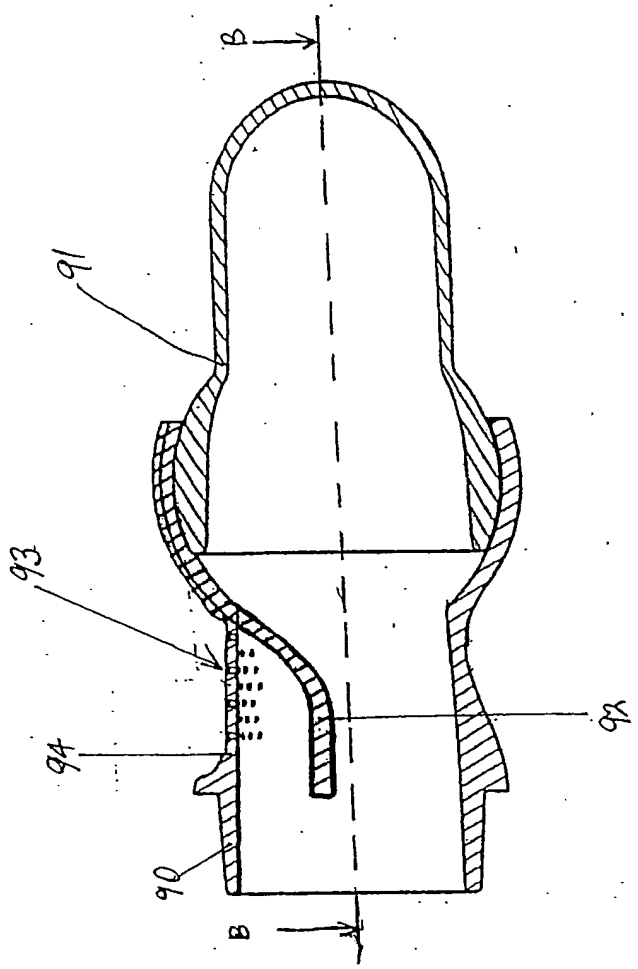


Figure 16

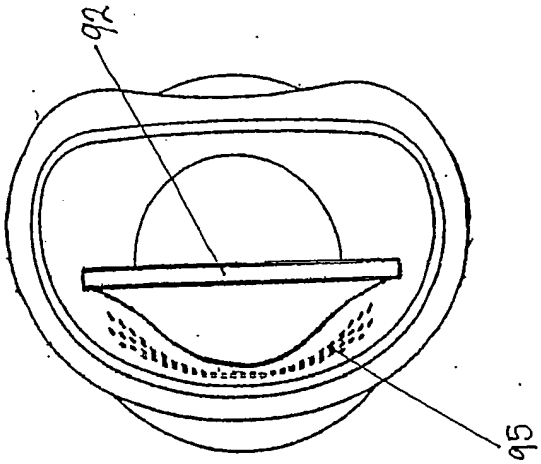


Figure 17